

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Determining the effect of quince fruit extract and apple cider vinegar on glycemic indices in adults with prediabetes: A double blind randomized clinical trial

Protocol summary

Study aim

Determining the effect of fruit extract and apple cider vinegar on glycemic indices in adults with prediabetes.

Design

Controlled, parallel-group, double-blind, randomized trial on 108 patients. Block randomization (block size 6, 18 blocks; allocation to intervention/control). Random sequence generated by a third party using Excel's rand function. Intervention and placebo identically packaged and coded. Principal investigator and patients blinded to allocation. Outcomes assessed by an independent third party not involved in treatment. Unblinding after final analysis.

Settings and conduct

The participants in this study have prediabetes and are selected through a call and referral by the attending physician of Taleghani Hospital Clinic. After explaining the purpose of the study, if desired, patients will refer to the laboratory of the Endocrine Sciences and Research Institute at the specified time. Patients are asked to fast for 12 hours on the day of visiting the clinic.

Participants/Inclusion and exclusion criteria

Inclusion criteria: cooperation, prediabetes, age 20-50, no smoking or alcohol, no specific diet, no weight change in last 3 months, non-pregnant or lactating, BMI 20-30. Exclusion criteria: lifestyle or drug change during trial, unwillingness to consume apple cider vinegar-quince mixture, hypersensitivity to apple cider vinegar, GI disorders (IBS/IBD).

Intervention groups

Patients with prediabetes will be randomly divided into 3 groups (2 intervention groups and 1 control group). In the first group, advise to consume one tablespoon of apple cider vinegar with a glass of water during each meal. In second group, advise to consume one tablespoon of fruit juice during each meal. In the third group, the control group will not receive anything.

Main outcome variables

Blood sugar control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160822029472N3**

Registration date: **2026-05-11, 1405/02/21**

Registration timing: **prospective**

Last update: **2026-05-11, 1405/02/21**

Update count: **0**

Registration date

2026-05-11, 1405/02/21

Registrant information

Name

Reza Homayounfar

Name of organization / entity

Shahid Beheshti university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2026-12-22, 1405/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effect of quince fruit extract and apple cider vinegar on glycemic indices in adults with prediabetes: A double blind randomized clinical trial

Public title

Effect of quince fruit extract and apple cider vinegar on glycemic indices

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to cooperate; Having prediabetes; Age between 20 and 50 years; No smoking or alcohol; No special diet; No weight change in the past 3 months; No pregnancy or breastfeeding; BMI between 20 and 30.

Exclusion criteria:

Intention to modify lifestyle or pharmacological therapy over the course of the study
Unwillingness to consume the mixture of apple cider vinegar and quince fruit
Known allergy or adverse reaction to apple cider vinegar
Presence of gastrointestinal diseases (irritable bowel syndrome and inflammatory bowel disease)

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

The design of this study is permuted block randomization, in which the participants are allocated to intervention and control groups using the Block Randomization method in 18 blocks (in 3 groups) with a Block size of 6. In this study, which will be conducted for 12 weeks, patients with prediabetes will be randomly divided into 3 groups (2 intervention groups and 1 control group). In the first group, it is recommended to consume one tablespoon of apple cider vinegar with a glass of water during each meal (breakfast, lunch, and dinner). In the second group, it is recommended to consume one tablespoon of fruit juice during each meal (breakfast, lunch, and dinner). In the third group, the control group receives nothing. In this study, the principal investigator will not be involved in the randomization process.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, blinding will be done for patients and researchers, and a person outside the research team will be selected to evaluate the results. Randomization will be done by a third person. In this way, patients and study researchers are not aware of the type of groups and the double-blind conditions of the study are maintained. Apple cider vinegar and fruit will be packaged and shipped in such a way that the difference between the two cannot be easily identified. At the end of the study, after the results are determined, the labels will be revealed by a third person and the information will be evaluated.

Placebo

Used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Nutrition Research Institute Ethics Committee

Street address

Hafezi Street

City

Tehran

Province

Tehran

Postal code

۱۹۸۱۶۱۹۵۷۳

Approval date

2025-05-18, 1404/02/28

Ethics committee reference number

IR.SBMU.nnftri.Rec.1404.014

Health conditions studied**1****Description of health condition studied**

Prediabetes

ICD-10 code

R73.01

ICD-10 code description

Impaired fasting glucose

Primary outcomes**1****Description**

Fasting plasma glucose

Timepoint

First, the sixth and twelfth weeks

Method of measurement

Enzymatic colorimetric method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Recommended to consume one tablespoon (5 ml) of apple cider vinegar with a glass of water during each meal (breakfast, lunch, and dinner).

Category

Treatment - Other

2

Description

Intervention group: In the second group, it is recommended to consume one tablespoon of fruit extract (5 ml) during each meal (breakfast, lunch, and dinner).

Category

Treatment - Other

3

Description

Control group: They don't receive anything.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Research Center, Royan Research Institute

Full name of responsible person

Seyed Hosein Davodi

Street address

Royan Center for Diabetes, Obesity and Metabolism,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed hosein davodi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No further information available.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available